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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,882

03/19/2004

Stephen James Field

0119/0034

7153

21395 7590 03/11/2008

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EXAMINER

ROY, BAISAKHI

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,882	<b>Applicant(s)</b> FIELD ET AL.	
	<b>Examiner</b> BAISAKHI ROY	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 7/2/07.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 3 - 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler and Sarkis alone in view of Koulik and further in view of Violante et al. (6106473). Rammler as earlier noted is directed to angioplasty catheter construction by interalia extrusion during which microbubbles are added per col. 3 lines 49 - 52. While the vane portion is thin per 5 - 100 mils this is due to the angioplasty application in small vasculature, and Rammler defines an inner and outer device, vane and track either of which may contain the microbubbles, the vane being thicker than the inner tubular member 44, 46 and the dilatable tube portion 42, and the track being thicker than the vane. Sarkis et al notes Rammler and discusses plastic echogenic catheter constructs where in terms of a pacing lead the inner or outer extruded polymer plastic sleeves 34, 38 or 40 of respective Figures 5 and 5 or either extruded catheter plastic layer 42, 44 of Fig. 6 or the outer tube or inner strut of Fig. 8 may be echogenically formed by mixing of echogenic particles within the extruded components. Accordingly it may be considered that Sarkis would teach complete layered catheter extrusion when combined with Rammler or conversely, Rammler as cited in Sarkis would evidence the equivalence of bubble mixing into the polymers being extruded into the various catheter wall

components of the latter as they are variously thickness apportioned, since Sarkis is simply noting that particle use as opposed to gas bubbles allows more echogenicity with less alteration of overall catheter properties.

3. In the alternative, Koulik may be added in supplement to evidence that when phase separated composition using an extractable material is prepared prior to the extrusion (col. 9 midportion) such as inter alia for the manufacture of any of a variety of catheters (col. 5 bottom and col. 9 lines 42 - 50) then microbubbles may be mixed in by an entrapped gas per col. 5 or using commercial LEVOVIST<sup>TM</sup> or ALBUNEX<sup>TM</sup> microbubble preparations col. 7 such that pore wall presumably thickness and associated characteristics may be adjusted, col. 2 lines 39 -41.

4. In the alternative Violante et al. may be added to supplement the use of coatings to provide highly echogenic devices for increased visibility from surrounding tissue under ultrasound imaging. Violante et al. teach applying a coating layer on the device containing the entrapped gas in enclosed bubbles (col. 5 line 51 - col. 6 line 26). The gaseous space is covered at the surface by a thin layer to enhance echogenicity while being flexible enough such that the gas remains compressible.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

/Brian L Casler/

Supervisory Patent Examiner, Art Unit 3737